REMARKS

Claims 1 and 5-11 constitute the pending claims in the present application. Among them, Claims 7 and 10 are directed to non-elected species, and are withdrawn from further consideration.

Applicant submits herewith a supplemental IDS, and respectfully request the Examiner to consider all the references cited therein.

On July 19, 2007, Applicant's attorneys Matt Vincent and Yu Lu interviewed Examiner Schlientz and his supervisor, Examiner Richter, to discuss the rejections and a proposed amendment. Examiner Richter acknowledged that he understands Applicant's efforts to define the treatable patient population, and would consider all evidence Applicant submits in favor of the amendment. The same was also stated in the Interview Summary, mailed on July 27, 2007. Thus this response also constitutes the required "written statement of the reasons presented at the interview as warranting favorable action" under 37 C.F.R. § 1.133(b).

Applicant respectfully requests reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

Claim Rejections under 35 U.S.C. § 112, second paragraph

Claim 11 is rejected for allegedly being indefinite, because it recites "formulas I-XVIII." The Examiner requests Applicant to recite the exact formulae in the claims, rather than incorporating these formulae into the claims by reference.

Applicant has amended Claim 11 to recite the specific formulae, thereby overcoming this rejection. Support can be found at, for example, pages 9-53. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph are respectfully requested.

Claim Rejections under 35 U.S.C. § 102

Claims 1, 5, 6, 8, 9, and 11 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by International Patent Application Publication WO 03/097011 A1 ("Barth"). The Office Action alleges that Barth "discloses a method of treating gastroesophageal reflex disease

(GERD) ... sleep disorders, sleep apnea and snoring..." The Office Action cited certain passages of Barth to support this contention. Applicant respectfully disagrees for the reasons which follow.

First of all, Applicant submits that **the art recognizes OSAS and (primary) snoring as two distinct disease conditions that may require different treatments**.

According to WebMD, OSAS (Obstructive Sleep Apnea Syndrome) is a serious condition linked to many health problems, including death. *See* **Exhibit A**. However, the same article also indicates that: "OSAS is different from primary snoring (PS), the name given to snoring that doesn't cause sleep disruption or breathing problems. Primary snoring is more common than OSAS, which occurs in about 2 percent of children ..." (emphasis added).

The article also warns that, from the diagnostic perspective, these two conditions cannot be distinguished from each other based on the history and physical examination alone. *Id.* Thus, it is critically important to differentiate *primary snoring* from *OSAS*, in order to properly diagnose the respective conditions and avoid tragic consequences. *See id.*

Therefore, it is apparent that *primary snoring* is a mild condition that neither causes sleep disruption nor breathing problems. In fact, many snoring patients may not even know that they have snoring problems. It is usually the other people (*e.g.*, spouses) sleeping with the snoring patients that are the most affected and complain.

In contrast, OSAS is a potentially fatal disease that *does* cause sleep disruption and/or severe breathing problems in OSAS patients themselves. It does so by blocking patients' breathing during sleep, thus *sometime, but not necessarily*, causing snoring. In other words, in some but not all OSAS patients, snoring may be a symptom. Applicant hereby submits **Exhibit B**, which is a WebMD information page about common sleep apnea symptoms (with information source coming from The National Sleep Foundation, and the National Institute of Health or NIH, last updated on January 1, 2007). Applicant notes that snoring is not listed as a common symptom associated with sleep apnea. *See* **Exhibit B**.

Consistent with this distinction, primary snoring and OSAS may require different treatments. For example, tonsillectomy and adenoidectomy (*i.e.*, surgeries that remove the tonsils and adenoids)

are surgeries used to treat OSAS in children and adults, but *rarely* used to treat snoring in adults, and not used to treat snoring in children. **Exhibit C**. In fact, surgery is "the most common treatment," and is "often the first treatment option" for OSAS children, "because enlarged tonsils and adenoids are usually the cause of their sleep apnea." **Exhibit C**. In contrast, such surgery is not used in children to treat primary snoring. Some insurance company may not consider snoring to be a medical problem, and may even refuse to pay for its treatment. *See* **Exhibit C**.

This indicates that one of skill in the art (*e.g.*, the medical community) clearly understand primary snoring as a condition distinct from OSAS, and a condition that may require a different treatment, despite the fact that snoring *may* (but not *necessarily*) become associated with OSAS.

Because of this understanding, when a patient complains to a doctor (one of skill in the art) about a snoring problem, the doctor must first decide whether the patient suffers from OSAS or primary snoring. If OSAS is found to be the cause, the doctor may perform surgery to treat the patient. But if OSAS is determined not to be the cause, the doctor will most likely not perform the surgery, but instead recommend certain snoring treatments such as life-style changes, *etc.*

Likewise, in view of Barth, if OSAS is found to be the cause, the doctor may prescribe GERD medicine to treat the patient, in the hope that secondary symptoms such as snoring will also be alleviated. But if OSAS is determined not to be the cause of snoring (as in the majority of the snoring patients), Barth provides no reason for the doctor to prescribe the GERD medicine to treat the patient who does not have OSAS.

Consistent with this art-recognized distinction, **the instant specification distinguishes primary snoring and OSAS (as well as other sleep disorders), and supports the treatment of both conditions**. *See*, for example, page1, last 3 paragraphs.

Specifically, although the term "primary snoring" is not explicitly used, the instant specification distinguishes OSAS from primary snoring by the degree of upper airway obstruction. For example, the specification defines "obstructive sleep apnea (OSA)" as a "condition of total functional collapse of the upper airway" (emphasis added). *See*, page 1, last paragraph. In contrast, the specification implies "snoring" as "a symptom of (partial) nocturnal upper airway obstruction"

(page 1, 3rd paragraph), because the specification teaches how to measure the "degree" of obstruction in snoring on page 54, 7th paragraph.

In view of the foregoing, Applicant has amended Claim 1 to further clarify the subject matter claimed. Applicant submits that amended Claim 1 is directed to a method of treating a condition known in the art as primary snoring, which is distinct from snoring that happens to become associated OSAS in some (but not all) OSAS patients. Therefore, this amendment distinguishes the cited art by excluding any snoring that happens to be associated with certain OSAS patients. Barth does not teach or suggest treating a patient with partial nocturnal upper airway obstruction, because Barth at best teaches treating those OSAS patients who happen to also have a snoring symptom. But in those OSAS patients, by definition, there is a total functional collapse of the upper airway, which is *not* partial nocturnal upper airway obstruction.

The Office Action argues that Barth teaches a method that *inherently* treats snoring, Applicant respectfully disagrees, because **the legal standard for inherent anticipation is not met**.

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient'" (emphasis added). *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Also see MPEP 2112: "[t]he fact that a certain results or characteristics may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)" (emphasis in original).

This is a strict standard, which requires necessity. Probability, possibility, or even near certainty (*e.g.*, "almost always") would not satisfy the legal standard. *See In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Therefore, if OSAS is the cause for all snoring (which isn't true), then it may be true that treating OSAS necessarily treats (secondary) snoring caused by OSAS.

However, this is not true. The majority of snoring patients do not have OSAS at all. *See* **Exhibit A** ("[p]rimary snoring is more common than OSAS"). Thus even if all OSAS patients snore (which Applicant does not concede), they still only constitute a minority of all snoring patients. Thus it may be said that a method for treating OSAS necessarily treats the associated (secondary) snoring, it simply makes no logical sense to say that a method for treating OSAS necessarily treats the unrelated primary snoring that does not even exist in OSAS patients.

Therefore, Barth cannot anticipate the claims as amended. Reconsideration and withdrawal of this objection are respectfully requested.

Claim Rejections under 35 U.S.C. § 103

Claims 1, 5, 6, 8, 9, and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over International Patent Application Publication WO 03/053221 A2 ("Ieni") in view of either Senior *et al.* or Xiao *et al.* The Office Action argues that "snoring is a symptomatic condition intrinsically associated with OSAS, administration of a therapeutically effective amount of a proton pump inhibitor, such as lansoprazole and omeprazole, would intrinsically treat not only OSAS, but also symptomatic conditions intrinsically associated therewith, such as snoring, as instantly claimed."

Applicant submits that this rejection is essentially the same as that based on Barth, and thus would also be overcome by the Claim 1 amendment above. Briefly, even assuming for the sake of argument that there is motivation to combine Ieni and Xiao / Senior, the combination still fails to teach all the limitations of the claimed invention.

As argued above, although *some* but not all of the OSAS (obstructive sleep apnea syndrome) patients may snore, a method of treating OSAS patients cannot inherently anticipate a method of

treating snoring patients for the same reason argued above. *See* MPEP 2112, "[t]he fact that a certain results or characteristics may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)" (emphasis in original).

Thus at least one of the three requirements for establishing a *prima facie* case of obviousness has not been met. Reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the above amendments, Applicant believes the pending application is in condition for allowance. Applicant believes no fee other than those authorized in the Amendment Transmittal (filed concurrently herewith) is due with this response. However, if any other fee is due, please charge our Deposit Account No. **18-1945**, from which the undersigned is authorized to draw under Order No. **SOHN-P01-001**.

Dated: August 16, 2007

Respectfully submitted,

By_____

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